Social Media, Rx Promotion, & FDA

Results of a survey of readers & followers of *Pharma Marketing News*, Pharma Marketing Blog, and @pharmaguy

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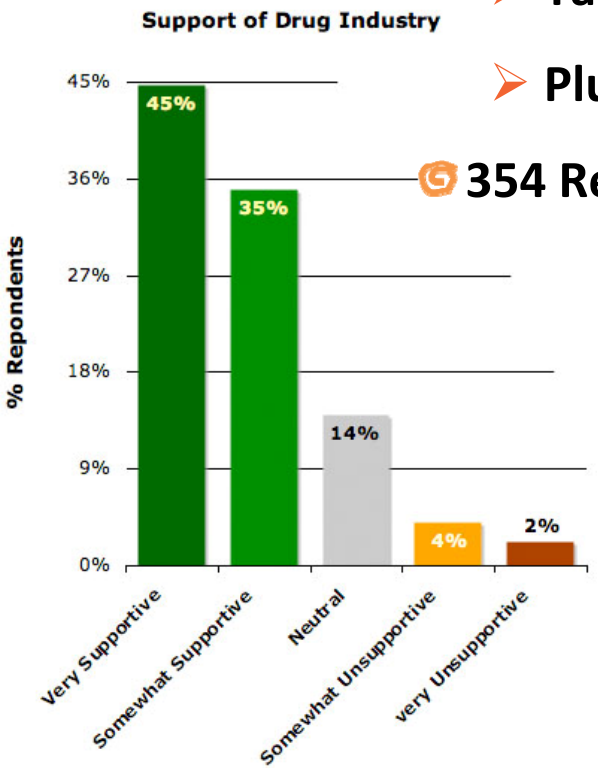
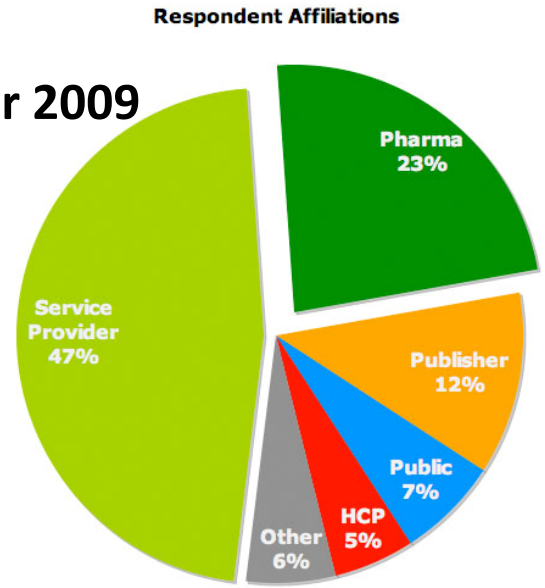
Pharma Marketing News

Survey Overview

- Online — started 20 September 2009
- Includes All 19 questions for which FDA seeks answers
  - Tallies votes on specific answers/solutions
  - Plus 575 comments
- 354 Respondents as of 1 November 2009
  - 126 Blog readers
  - 101 PMN subscribers
  - 64 Twitter followers
  - 45 Web site visitors





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Part 2

- Adverse Event Reporting

Adverse Events: Summary of Findings

- **Vast majority of "Adverse Experiences" reported on social media sites do NOT meet the requirements for AE reporting**
  - **Great majority of respondents (up to 87%) agree***
- **Although there are monitoring tools available, the resources required to monitor all social media sites for adverse events are not justifiable**
- **Consequently, few companies have standard operating procedures for processing adverse event information from social media sites**
- **However, pharma companies can help consumers report adverse events directly to the FDA using social media tools such as widgets placed on drug.com Web sites (see slide # 9).**

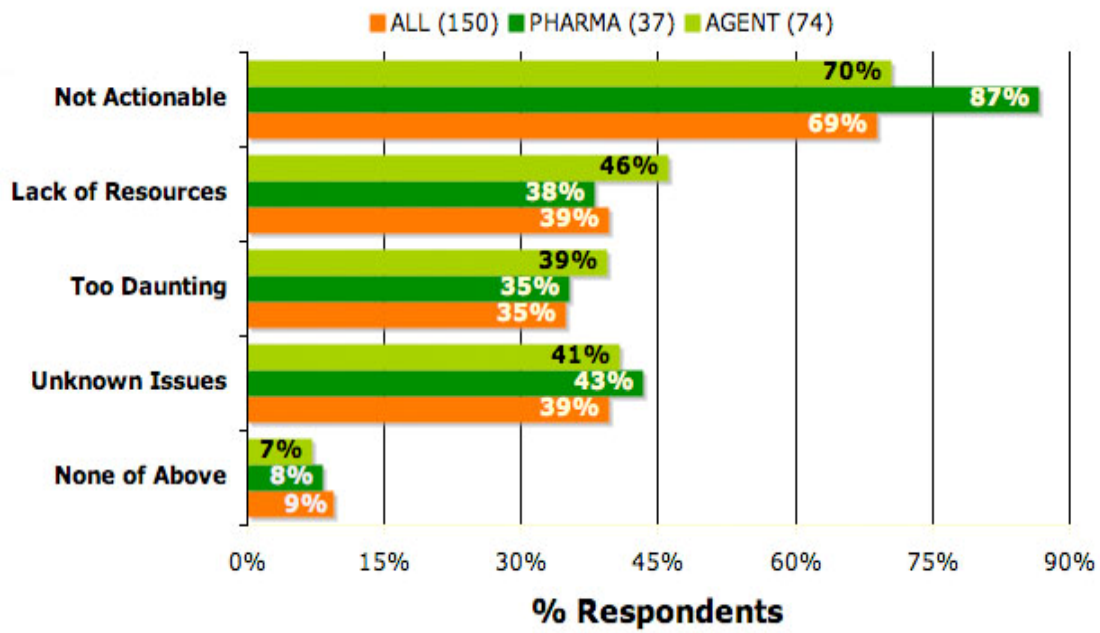
* See slide #5

Social Media AE Challenges

Adverse Event Reporting

What challenges are presented in handling adverse event information from these sources?

- The amount of information from these sources is potentially too vast to be processed economically (lack of resources)
- Finding adverse event information from these sources is like finding a needle in a haystack (too daunting)
- The information is usually incomplete and does not meet the requirements for submitting a meaningful AER (not actionable)
- There are many potential issues that won't fully be known until the practice of monitoring social media for AEs is more prevalent (unknown issues)



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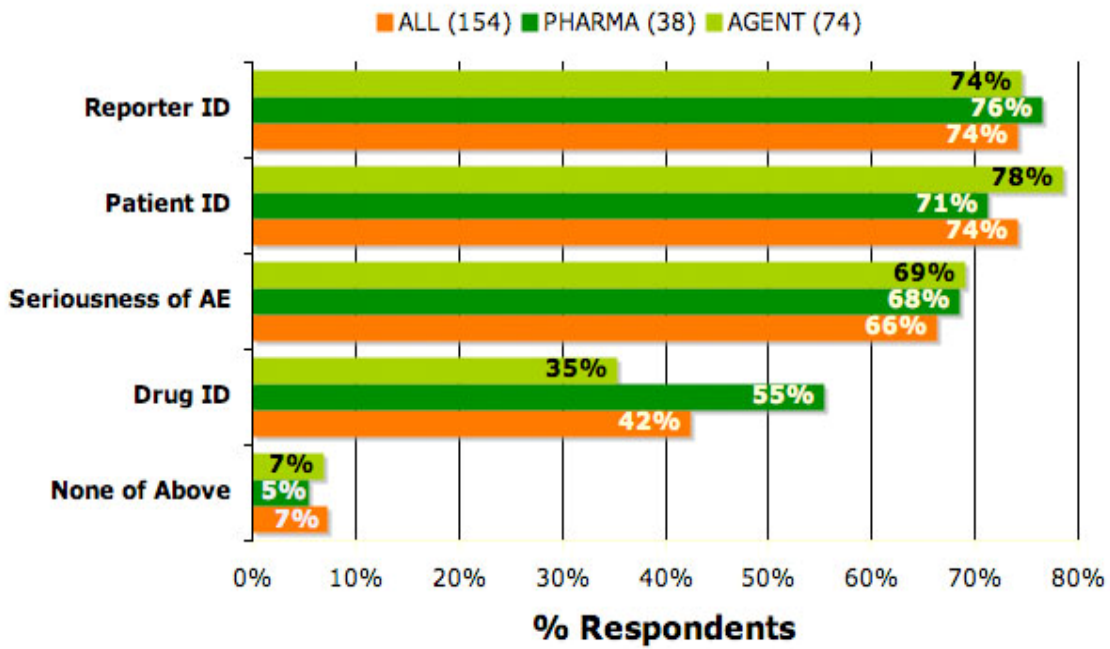
Social Media AE Uncertainties

Adverse Event Reporting

What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

- **Uncertainty regarding the true identity of the reporter (anonymous source)**
- **Uncertainty regarding the true identity of the patient (no patient named)**
- **Uncertainty regarding the identity of the drug (eg, reporter refers to "sleep pill" rather than brand name of drug)**
- **Uncertainty regarding the seriousness of the event reported**

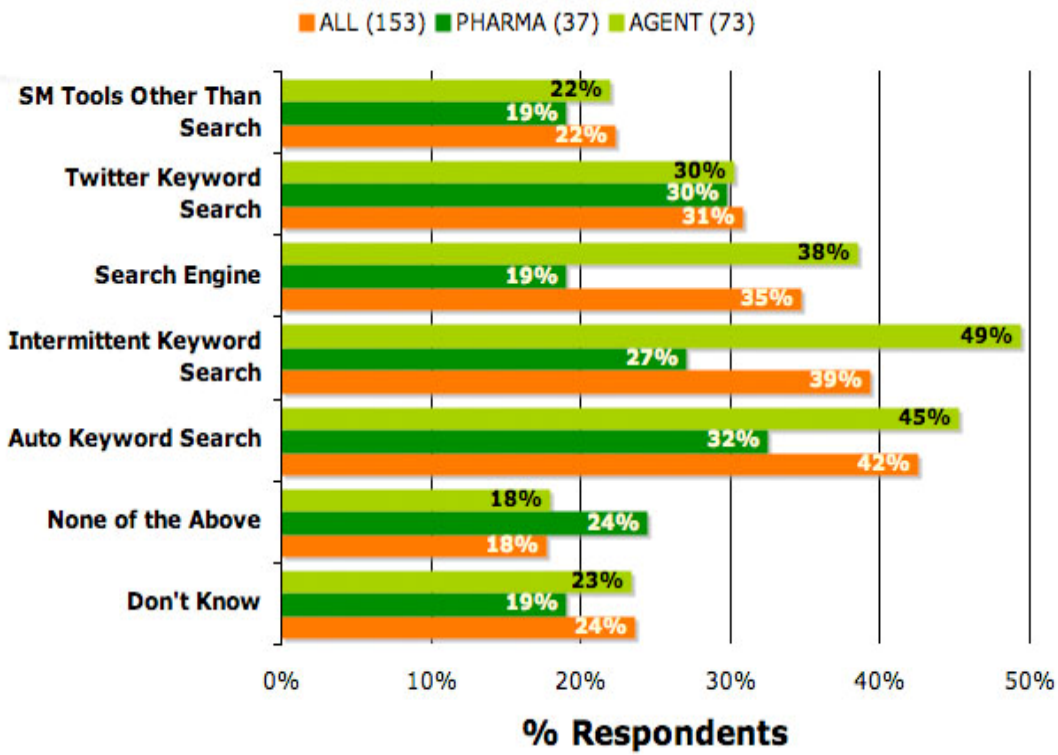


Monitoring AEs on Social Media Sites

Adverse Event Reporting

How are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products?

- Use of automated keyword searches of selected social media sites by specialized agencies and/or professionals
- Intermittent searches of selected social media sites performed by company personnel or agents
- Intermittent searches of SEARCH ENGINES performed by company personnel or agents
- Routine and automated keyword searches of TWITTER (eg, performed by SocialOomph or other services)
- Use of social media monitoring tools that do not include keywords



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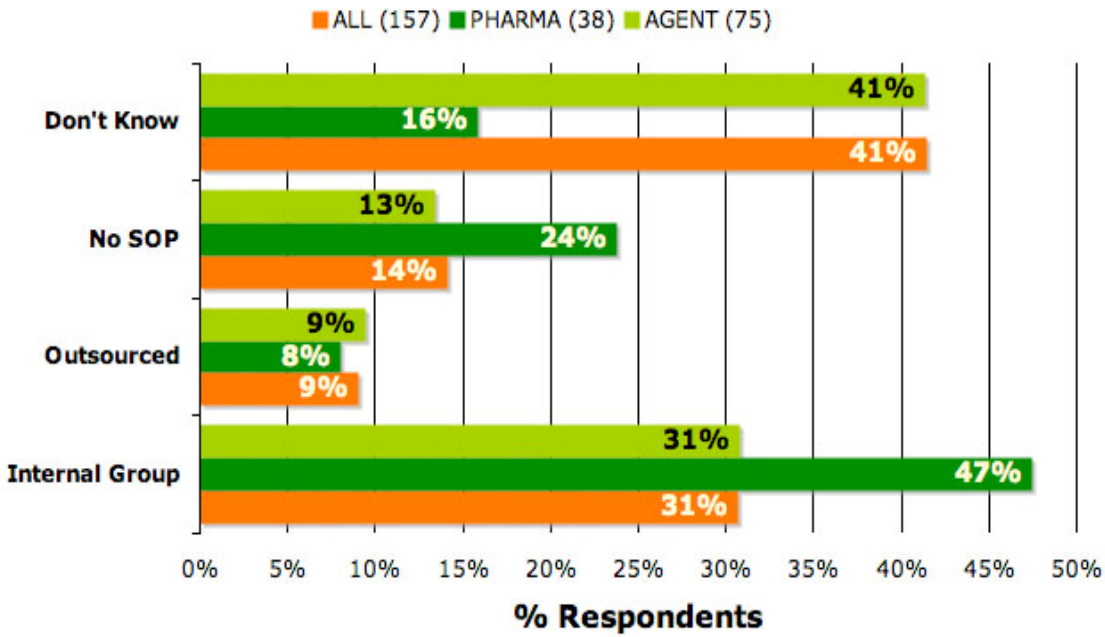
Processing Social Media AE Information

Adverse Event Reporting

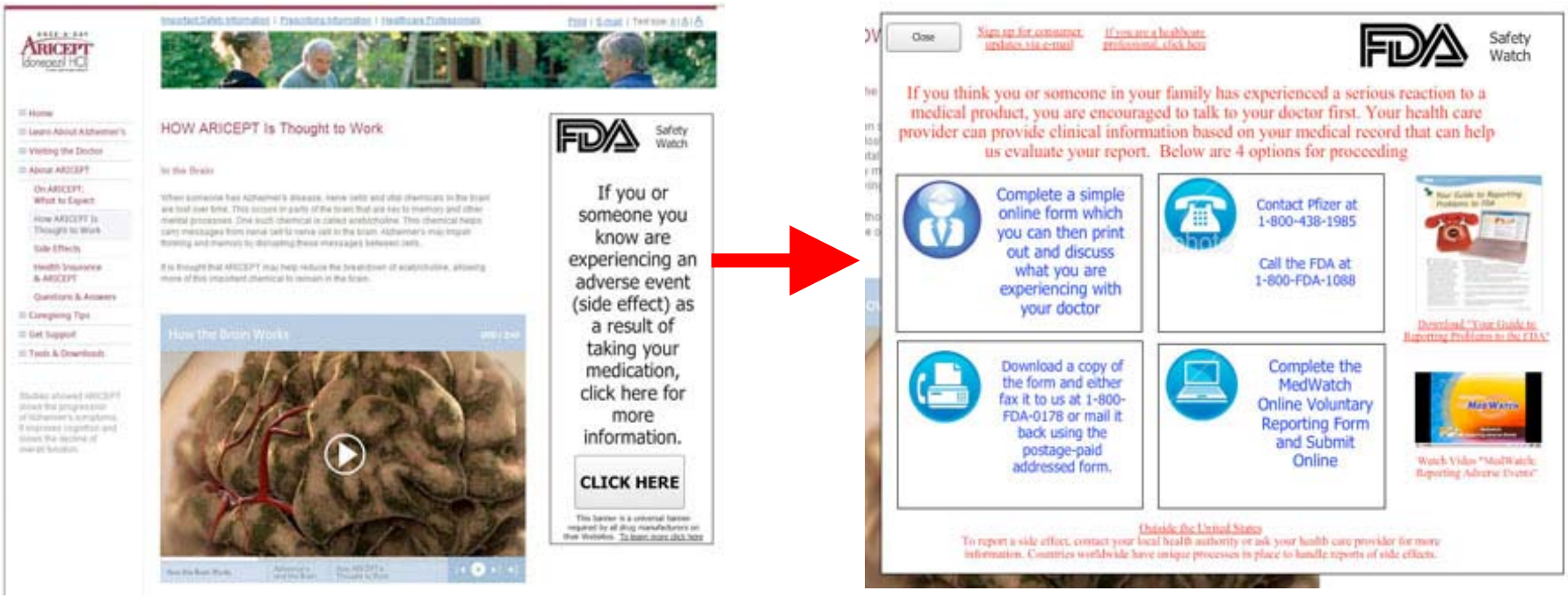
How is adverse event information from these sources being received, reviewed, and processed?

- **Special group within the company is responsible for receiving, reviewing, and processing AEs**
- **Receiving and processing AEs is outsourced to a specialized agency; review is handled in-house to determine which AEs need to be reported as required by law**
- **We have no SOP (Standard Operating Procedure) for receiving, reviewing, and processing AEs from these sources**



AE Reporting Safe Harbor Widget

"One-Click" Access to FDA and/or Pharmaco AE Reporting System



Pharmaceutical companies that post approved widgets on their drug.com Web sites should be allowed to monitor 3rd-party social media sites without the need to report any potential adverse events they may come across.

On Sale Outside or Online

Hoping for Helpful Guidelines, but Not Expecting Any

Availability: In stock. Usually ships within 24 hours.

Order and pay for this T-shirt now using your credit card...
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Add to Cart

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